

**EXHIBIT A**

**Defendants’ Objections to the Statement of Plaintiff’s Expert Cheryl Blume, Ph.D.**

Defendants Pfizer Inc. and Warner-Lambert Company LLC respectfully raise the following objections to the Statement of Plaintiff’s Expert Cheryl Blume, Ph.D., who is designated to testify about regulatory and causation issues.

TESTIMONY	OBJECTIONS
¶ 2: “I have been asked to investigate and provide opinions about whether Warner Lambert and Pfizer failed to warn doctors and patient...”	<ul style="list-style-type: none"><li>Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li></ul>
¶ 6: “It is also important for me to tell you that what I did here is the same tasks that I provide to drug companies outside of litigation. I used the very same methods as I have been using for the past 25 years.”	<ul style="list-style-type: none"><li>Witness refused to disclose information concerning her work and “tasks” for drug companies outside of litigation. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on November 12, 2007 at pp. 22-25.</li></ul>
¶ 10: “It was approved to treat epilepsy and for the treatment of post-herpetic neuralgia --- a very limited type of nerve pain, also called “shingles”.”	<ul style="list-style-type: none"><li>Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li><li>Referring to post-herpetic neuralgia as a "very limited type of pain" is beyond the expertise of the witness and is misleading (FRE 403)</li></ul>
¶ 12: “Also let me be clear: just because FDA has found the drug’s benefits outweighed the risk for uses like epilepsy and shingles pain, there is no proof that FDA ever decided the drug was safe for anything else.”	<ul style="list-style-type: none"><li>Lack of foundation. There is no reliable scientific evidence that safety has any relationship to the indication for use. (FRE 702)</li></ul>
¶ 13: “Because the defendants were actually marketing and promoting Neurontin for unapproved, “off-label” uses far beyond these limited FDA approvals. Doing this placed the public at risk of being harmed, and Mr. Smith is the victim of the Defendants’ actions.”	<ul style="list-style-type: none"><li>Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li><li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li></ul>

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	<ul style="list-style-type: none"> <li>• Lack of foundation. There is no reliable scientific evidence that safety has any relationship to the indication for use. (FRE 702)</li> <li>• Improper and personal opinion characterizing Mr. Smith as "victim" of Defendants' actions.</li> </ul>
<p>¶ 13: "Patients like Mr. Smith were not warned about the potential for suicide-related side effects with Neurontin."</p>	<ul style="list-style-type: none"> <li>• Any opinion that Defendants failed to warn "patients" is irrelevant, misleading and likely to confuse the jury under Tennessee's learned intermediary doctrine. (FRE 402, 403)</li> </ul>
<p>¶ 14: "Based on my review of documents, Pfizer wasn't careful and people like Mr. Smith died."</p>	<ul style="list-style-type: none"> <li>• Improper personal opinion without any reliable scientific basis; improper characterization of Defendant's conduct; not supported by any discernable regulatory requirement; unreliable; will not assist the trier of fact. (FRE 702)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time. (FRE 403)</li> <li>• Witness is not a specific causation expert.</li> </ul>
<p>¶ 22: Even though the Defendants were fully aware that the drug could have these effects, the company marketed the drug "off label" to the very individuals who were most vulnerable. Yet this very critical safety information was withheld from doctors and patients.</p>	<ul style="list-style-type: none"> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• There is no duty under Tennessee law for a pharmaceutical company to warn patients directly under the "learned intermediary doctrine."</li> </ul>
<p>¶ 23: There are certain chemicals in the brain that effect how we feel. These are called</p>	<ul style="list-style-type: none"> <li>• Dr. Blume concedes in her May 7, 2010 deposition that one or more specific</li> </ul>

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<p>neurotransmitters. You have already heard [<i>or will hear Plaintiff's expert</i>] Dr. Michael Trimble talk about these chemicals. <u>When there is an increase or imbalance in these brain chemicals, people can get depressed and suicidal.</u> Now the defendants knew that Neurontin affected these chemicals. This document <b>proves</b> Defendants admit that Neurontin affects neurotransmitters in the brain <u>since the 1980s</u>. This is a copy of Defendants' confidential research study from May 1984, which showed that Neurontin reduced the release of excitatory neurotransmitters like serotonin and norepinephrine. This is important because these effects could contribute to suicidal behavior. (bold supplied for emphasis by defense counsel)</p> <p>¶ 25: Entire paragraph</p>	<p>mechanisms directly linking these drugs with the acts of self-injury or suicide-related behaviors have not been identified. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at page 32. She further stated the causation mechanism is not "relevant" to a regulatory opinion.</p> <ul style="list-style-type: none"> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• Improper summary and comment on testimony without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> <li>• Duplicative to testimony of Dr. Michael Trimble. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at pages 32 and 33 where witness testifies that other experts will testify concerning mechanisms of causation.</li> </ul>
<p>¶ 23: "For doctors treating vulnerable patients with psychiatric and pain conditions, this is critical information that was not in the label. Otherwise it was 'don't ask, don't tell' and business as usual."</p>	<ul style="list-style-type: none"> <li>• Improper personal testimony without scientific basis unsupported by any discernible regulatory requirement; unreliable; and will not assist the trier of fact.</li> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>
<p>¶ 24: Entire paragraph</p>	<ul style="list-style-type: none"> <li>• Rule of completeness (FRE 106)</li> <li>• Partial reference to deposition testimony, which should entitle defendant to play or read other parts of deposition</li> </ul>
<p>¶ 26: "What this means is that 19 people who</p>	<ul style="list-style-type: none"> <li>• Foundation, witness is not a clinician</li> </ul>

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had no psychiatric problems before receiving Neurontin, later needed drug therapy for treatment of the depression triggered by Neurontin."	<p>and lacks knowledge, skill, experience, training, or education regarding what triggers depression (FRE 702)</p> <ul style="list-style-type: none"> <li>• Outside scope of expert report. <i>See</i> ¶ 45 of Blume report.</li> </ul>
¶ 27: "What this means is that the Neurontin in certain patients made their behavioral problems worse."	<ul style="list-style-type: none"> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>
¶ 28: "While the increase could be due to more people using the drug, it could also be due to the drug causing the effect in a vulnerable population, such as patients at increased risk for these events because of underlying diseases."	<ul style="list-style-type: none"> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> <li>• Speculation</li> <li>• Foundation, witness is not a clinician and lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>
¶ 29: "Most critical is that despite both of these charts, the labeling wasn't changed and off-label use was skyrocketing."	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Outside scope of expert report. <i>See</i> ¶¶ 168-172 of Blume report.</li> </ul>
Exhibit 4147 (referenced in ¶ 36)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Hearsay within hearsay (FRE 802, 805)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice (FRE 403)</li> <li>• Irrelevant (FRE 401, 402, 407)</li> </ul>

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	<ul style="list-style-type: none"> <li>Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> </ul>
Exhibit 2061 (referenced in ¶ 37)	<ul style="list-style-type: none"> <li>Irrelevant (FRE 401, 402, 407)</li> <li>Subsequent remedial measures (FRE 407). Document Gabapentin Capture Aid was created in 2006.</li> </ul>
¶ 37: Entire paragraph concerning Gabapentin Capture Aid	<ul style="list-style-type: none"> <li>Subsequent remedial measures (FRE 407). Document Gabapentin Capture Aid was created in 2006.</li> </ul>
¶ 37: "This shows that the company agrees that it was appropriate to combine the suicide related terms, just as I did a few moments ago."	<ul style="list-style-type: none"> <li>Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>Improper state of mind testimony</li> <li>Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>
¶¶ 38-41: All paragraphs	<ul style="list-style-type: none"> <li>Chart created by plaintiff's counsel. Witness concedes inability to recreate, test or validate work that created chart. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken November 12, 2007 at pp. 69, 97-98, 102-103</li> <li>Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been</li> </ul>

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	reliably applied to the facts of the case (FRE 702)
Exhibit 4159 (Referenced in ¶¶ 43-45)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> <li>• Probative value substantially outweighed by danger of unfair prejudice (FRE 403)</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> </ul>
¶ 42: "Unfortunately for Mr. Smith, the company only did this because FDA required the company to review the information. This chart was created at a time that the company was already aware that the FDA had concluded that Neurontin and other drugs increased the risk of suicidal behavior."	<ul style="list-style-type: none"> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>
¶¶ 43-45: All paragraphs	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802). Chart cited was prepared by plaintiff's counsel.</li> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> <li>• Foundation, not based upon sufficient facts or data, is not the product of reliable principles and methods, and the principles and methods have not been reliably applied to the facts of the case (FRE 702)</li> <li>• Any opinion that Defendants failed to</li> </ul>

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	<p>warn "patients" is irrelevant, misleading and likely to confuse the jury under Tennessee's learned intermediary doctrine. (FRE 402, 403)</p>
<p>¶ 46: Now, Defendants may say the words "suicidal" or "suicide gesture" were included in the premarketing labeling events for Neurontin, but this was only in their laundry list of side effects. This was simply not good enough in terms of adequately providing doctors and patients with directions to use Neurontin safely, particularly in light of the postmarketing evidence I have shown you today.</p>	<ul style="list-style-type: none"> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> <li>• Witness is not a physician and should not be permitted to opine what is "good enough for physicians."</li> <li>• Misstates duty of pharmaceutical company to warn patients directly.</li> </ul>
<p>¶ 47: Entire paragraph</p>	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> <li>• Witness is not a physician and should not be permitted to opine what is "good enough for physicians."</li> <li>• Misstates duty of pharmaceutical company to warn patients directly.</li> </ul>
<p>¶ 48: "So, don't believe the defendants if they claim that they ever warned for "suicide" during Mr. Smith's life."</p>	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Improper summary and comment on</li> </ul>

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	<p>evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</p> <ul style="list-style-type: none"> <li>• Improper opinion not previously disclosed (FRCP 26(a)(2)(B) and 37(c)(1))</li> </ul>
Exhibit 2001 (Referenced in ¶ 50)	<ul style="list-style-type: none"> <li>• Hearsay (FRE 802)</li> <li>• Hearsay within hearsay (FRE 802, 805)</li> <li>• Probative value substantially outweighed by danger of unfair prejudice (FRE 403)</li> <li>• Irrelevant (FRE 401, 402, 407)</li> </ul>
¶¶ 50-51: Entire paragraphs	<ul style="list-style-type: none"> <li>• Any opinion that Defendants failed to warn “patients” is irrelevant, misleading and likely to confuse the jury under Tennessee’s learned intermediary doctrine. (FRE 402, 403)</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>
¶ 54: Entire paragraph.	<ul style="list-style-type: none"> <li>• Outside scope of expert report.</li> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>
¶ 55: “This is a document from 1999 that predates Pfizer purchasing Warner-Lambert. In contrast to the defense noted above,	<ul style="list-style-type: none"> <li>• Incomplete quotation; rule of completeness (FRE 106)</li> </ul>



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Christopher Wohlberg describes Neurontin as the 'snake oil of the 20th century'."	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> </ul>
Exhibit 5809 (Referenced in ¶¶ 57-59)	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Irrelevant (FRE 401, 402, 407)</li> <li>• Not proper subject for expert testimony</li> </ul>
¶ 57: Entire paragraph	<ul style="list-style-type: none"> <li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li> <li>• Irrelevant as 2009 discussions with FDA as to content of class label for AEDs does not bear on any issue of liability or damages in this case (FRE 401, 402, 407)</li> </ul>
¶ 59: "However, other authors who are not hired by Defendants ..."	<ul style="list-style-type: none"> <li>• Improper summary and comment on evidence without scientific analysis; improperly usurps role of jury to determine significance of and inferences from evidence; not proper expert testimony. (FRE 702)</li> </ul>
¶ 61: "These authors (at page 1406) found that 'the risk of attempted or completed suicide was meaningfully increased for gabapentin. They do indicate that there is 'no clear understanding of a mechanism of action that could lead to	<ul style="list-style-type: none"> <li>• Incomplete quotation; rule of completeness (FRE 106)</li> <li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li> </ul>

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suicidal behavior,' but then they go ahead and say that Gabapentin has been 'associated with behavioral problems such as aggression and hyperactivity...'"	<ul style="list-style-type: none"><li>• Witness could not answer questions in deposition about whether aggression and hostility include suicide or suicide attempts. <i>See</i> Deposition of Cheryl Blume, Ph.D. taken on May 7, 2010 at page 42, lines 5-13.</li></ul>
¶ 62: Entire paragraph	<ul style="list-style-type: none"><li>• Probative value substantially outweighed by danger of unfair prejudice, confusion of the issues, and misleading the jury, and by considerations of undue delay and waste of time (FRE 403)</li><li>• Any opinion that Defendants failed to warn "patients" is irrelevant, misleading and likely to confuse the jury under Tennessee's learned intermediary doctrine. (FRE 402, 403)</li><li>• Foundation, witness lacks knowledge, skill, experience, training, or education (FRE 702)</li></ul>

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